DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
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March 24, 2005

Armed Forces Epidemiological Board

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Ladies and Gentlemen:

This letter corresponds to your Docket Number 1980N-0208, Final Rule & Final Order Involving Bacterial Vaccines and Toxoids.

On behalf of the Armed Forces Epidemiological Board (AFEB), a civilian scientific advisory body to the Assistant Secretary of Defense for Health Affairs and the military Surgeons General chartered by the Administrative Assistant to the Secretary of Army under the Federal Advisory Committee Act, we strongly endorse the Food & Drug Administration's (FDA) proposed text for the Final Rule & Final Order Involving Bacterial Vaccines and Toxoids, as published on December 29, 2004, in the *Federal Register*.

The AFEB has periodically deliberated on the use of anthrax vaccine in the military, and has issued a number of recommendations to the Department of Defense supporting the use of this product as an appropriate force protection measure.

The proposed Final Rule & Final Order is based on objective medical evidence and is consistent with the findings of the 1978 and1985 Panels to Review Bacterial Vaccines and Toxoids, which concluded that anthrax vaccine adsorbed, USP (*BioThrax*, BioPort Corporation) is effective in preventing anthrax, regardless of the route by which spores enter the body. The results of a human field trial and non-human primate lethal challenge studies support this conclusion.

In addition, the AFEB supports the 2002 report of The National Academy of Sciences which found that both cutaneous and inhalation forms of anthrax share a common pathophysiology. The same toxins are secreted regardless of the route of entry and produce the same pathology at the cellular level. Anthrax vaccine stimulates production of neutralizing antibodies against Protective antigen (PA), a protein produced by anthrax bacteria essential for anthrax disease to develop in humans. Without PA, anthrax bacteria cannot cause human disease regardless of exposure route.

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While we recognize that correlates of immune protection between human and non-human primates are not fully developed, anthrax challenge studies conducted in rhesus monkeys support the inference that anthrax vaccine is effective against inhalational anthrax in humans. In a series of studies, 65 vaccinated monkeys were challenged with doses of anthrax bacteria at several times the median lethal dose. Sixty-two of 65 vaccinated monkeys survived (95% survival) while 18 of 18 (100%) in the unvaccinated control group died.

As a scientific body consisting of senior civilian scientists and academicians advising the Department of Defense, we routinely observe the inner workings of the Department with respect to health concerns and health policy. It has been our experience that, contrary to concerns by some groups, the Department has willingly shared information on issues related to the health and well-being of military service members and their families. Across a variety of health issues, from infectious diseases, occupational and environmental exposures, and health promotion and maintenance programs, the AFEB has observed frank and open discussions by DoD health care providers. The Department's senior leaders are intent on optimizing the health and well-being of those to whom it provides care. DoD has repeatedly engaged the AFEB and other scientific bodies to ensure that the best available science is applied to the decision-making process. With respect to anthrax vaccine, DoD has shared with independent panels of civilian physicians and scientists, their experience from administering more than 5 million doses of anthrax vaccine.

It is the AFEB's view that anthrax vaccine adsorbed, USP (*BioThrax*, BioPort Corporation) is safe and effective in preventing anthrax regardless of exposure route. The continued availability of this vaccine is important to national security. Based on the Board's interaction with DoD and review of study findings, it is our conclusion that the Department is fully capable of continuing to implement quality vaccination programs based on the best available science while remaining sensitive to the needs of each service member.

In summary, the AFEB fully supports the FDA's conclusions as stated in the proposed Final Rule and Final Order. If the AFEB can be any further service or assistance with respect to this issue, please do not hesitate to contact the AFEB through the Executive Secretary, Dr. Roger Gibson, at 703-681-8014.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

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